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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/224,558	12/30/98	SCHROIT A	UTSC:594

HM12/0129

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EXAMINER	
NICKOL,G	
ART UNIT	**PAPER NUMBER**
1642	11

DATE MAILED: 01/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/224,558	Applicant(s) SCHROIT, ALAN J.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,12 and 28-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12 and 28-43* is/are rejected.

7)☒ Claim(s) *8,44* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Response to Amendment

The Amendment filed November 6, 2000 (Paper No. 10) in response to the Office Action of August 1, 2000 is acknowledged and has been entered. Claims 1-8, 11-12, and 28-44 are pending. Claims 1, 7, 12, 39, and 43-44 have been amended. Claims 1-8, 11-12, and 28-44 are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Objections Maintained

Claims 8 and 44 remain objected to for the reasons of record in Paper No. 9, page 2.

Rejections Maintained

35 USC 112 2nd Paragraph

Claim 11 remains rejected under 35 USC 112 2nd paragraph for the reasons of record in Paper No. 9, page 3. Applicant argues (Paper No. 10, page 3) that Claim 11 has been cancelled. The argument has been considered but is not found persuasive because the response in Paper No. 10 did not include any request for claim cancellations. Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

35 USC 102

Claims 1-6, 11-12, and 28-42 remain rejected under 35 USC 102(b) as being anticipated by Creaven, P (US Patent No. 4,994,440, 1991) or (UCLA Symp. Mol. Cell. Biol, 1989) for the reasons of record in Paper No. 9, pages 6-8.

Applicant argues (Paper No. 10, page 4) that the response mediated by the administration of the composition as taught by Creaven is a non-specific macrophage-mediated response wherein the claims, as amended, are directed towards the elicitation of an antigen-specific response, i.e. a humoral or cellular response. The argument has been considered but is not found persuasive. The inclusion of an "antigen-specific" response does not exclude macrophage-mediated killing of tumor cells because those of skill in the art recognize that macrophages are considered accessory cells in humoral immunity (Janeway et al., Immunobiology, 1994, page 1:32) wherein macrophages are primarily phagocytic in that they engulf antibody-coated pathogens which are destroyed in intracellular vesicles following pathogen uptake. Further, Tannock et al. (The Basic Science of Oncology, 2nd edition, 1992, page 247, 1st column) teach that macrophages can be activated to kill tumor cells wherein injection of lipid/polypeptide constructs (muramyl dipeptide in lipid vesicles) allowed for preferential trapping and phagocytosis by macrophages in the lung resulting in the successful treatment of lung metastases from experimental tumors in mice. Further, those of skill in the art recognize that macrophages elicit cell-mediated immune responses. Macrophages are known as professional antigen presenting cells found in all areas of the lymph node and actively ingest particulate antigens wherein they are able to process and present antigens to naïve T cells (Janeway et al. page 7:4 and 7:5).

Applicant's further argue that, MTP-PE, is the immunostimulatory component of the composition and that the lipid of the composition is of little relevance in the induction of the immune response. The argument has been considered but is not found persuasive. Applicant is arguing limitations not set forth in the claims. Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See In re Philips Industries, Inc. v. State Stove & Mfg. Co., 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. Applicant is reminded that the claims define the subject matter of the invention, and that the specification cannot be relied upon to read limitations into the claims. Arguments presented that rely on particular distinguishing features are not persuasive where those features are not recited in the claims.

Therefore, Applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1, 5-6, 11, and 28 remain rejected under 35 USC 102(b) as being anticipated by Fidler et al. (US Patent No. 4,916,118, 1990) for the reasons of record recited in Paper No. 9, pages 8-9.

Applicant argues that the amended claims are directed towards the elicitation of an antigen specific response, *i.e.* a humoral or cellular response, wherein an person of ordinary skill would recognize that the ability to activate macrophages would not equate to the ability to initiate the immunological cascade necessary to facilitate the development of an antigen specific humoral or cellular response. This argument has been considered but is not found persuasive for the reasons set forth above.

Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

35 USC 103(a)

Claims 1-7, 11-12, and 28-43 remain rejected under 35 USC 103(a) as being unpatentable over Creaven, P (US Patent No. 4,994,440, 1991) or (UCLA Symp. Mol. Cell. Biol, 1989) in view of Gupta et al. (Vaccine, v.13, No. 14, 1995) for the reasons of record in Paper No. 9, pages 9-11.

Applicant argues that response elicited in the method taught by Creaven is a non-specific macrophage mediated response and would not equate to the ability to initiate the immunological cascade necessary to facilitate the development of an antigen specific humoral or cellular response. Applicant further argues, that nevertheless, Gupta et al. does not instruct one of ordinary skill on how to modify a macrophage response in order to establish an antigen specific response. The argument has been considered but is not found persuasive for the reasons recited above with regard to the teachings of Creaven. Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination

of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

New Objections

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no support in the specification for "antigen specific" in the amended claims.

New Rejections

Claims 1-8, 11-12, and 28-44 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a "antigen specific" immune response has no clear support in the specification and the claims as originally filed. Applicant's allege that support for the amendments may be found throughout the specification, such as page 4, lines 10-14. The suggested support is not found persuasive because there is nothing in the specification which clearly indicates that the immune response is "antigen specific". The subject matter claimed in claims 1-8, 11-12, and 28-44 broadens the scope of the invention as originally disclosed in the specification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
January 18, 2001

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